K002288

510(k) Premarket Notification
Arndt Pediatric Endobronchial Blocker
COOK INCORPORATED

NOV 2 8 2000

Safety and Effectiveness Information

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235

Device: Trade Name: Arndt Pediatric Endobronchial Blocker
Proposed Classification Name: Tracheal/Bronchial Differential Ventilation Tube

Predicate Devices or Legally Marketed Devices:

Bronchial Blocker	Marketed & Distributed by COOK INCORPORATED
Univent Tube	Marketed & Distributed by Vitaid, LTD

Device Description

The catheter contains a balloon at its distal tip. The proximal end of the catheter is made up of a Y-fitting. One port of the Y-fitting is connected to a pilot balloon assembly. This balloon assembly facilitates inflation of the distal balloon and maintains inflation until it is released. The other port of the Y-fitting connects to the through lumen of the catheter which incorporates a removable looped guide wire that is used to help traverse the catheter along the length of a previously positioned bronchoscope. When the balloon catheter has been advanced to either the right or left bronchus, the guide loop is removed and discarded leaving the through lumen open.

Indications for Use

The Arndt Pediatric Endobronchial Blocker is intended for use to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures which require one-lung ventilation.

Substantial Equivalence

The Arndt Pediatric Endobronchial Blocker is similar to the Cook Bronchial Blocker and the Univent Tube. The Arndt Pediatric Endobronchial Blocker is a modification of the Cook Bronchial Blocker manufactured and marketed by Cook (D.C. #K962167). The Univent Tube was cleared under Premarket Notification #K894337. The similar indications for use and technological characteristics of the Arndt Pediatric Endobronchial Blocker as compared to the predicate devices support a determination of substantial equivalency.

Test Data

The Arndt Pediatric Endobronchial Blocker was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- Performance Testing
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a Bronchial Differential Ventilation Tube.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2000

Ms. April Lavender
Cook Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Re: K002288
Arndt Pediatric Endobronchial Blocker
Regulatory Class: II (two)
Product Code: 73 CBI
Dated: November 10, 2000
Received: November 13, 2000

Dear Ms. Lavender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002288

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002288

X Prescription use ___ Over-the-counter

(Optional Format 3-10-98)